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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/895,263

07/02/2001

Wei Wu He

PF140C2

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22195

7590

09/27/2002

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,263

Applicant(s)

HE ET AL.

Examiner

Gabriele E. BUGAISKY

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to nucleic acids encoding ICE-LAP 3 and 4, and a recombinant method of producing the proteins classified in class 435, subclass 69.1.
- II. Claims 19-21 and 24-25, drawn to ICE-LAP 3 and 4, pharmaceutical and pharmaceutical treatment method comprising the proteins classified in class 424, subclass 94.65.
- III. Claim 22, drawn to antibodies specific for ICE-LAP 3 and 4, classified in class 530, subclass 387.9.
- IV. Claims 23 and 26-27, drawn to modulators of ICE-LAP 3 and 4 and treatment methods with them, classified in class 514, subclass 1.
- V. Claims 24, 25, 28 and 29, drawn to methods of gene therapy, classified in class 514, subclass 44.
- VI. Claim 30, drawn to a method for detection of ICE-LAP 3 and 4 encoding sequences, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

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product as claimed can be either purified from natural sources or made by chemical synthesis such as the Merrifield procedure.

Inventions I and III and I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. An antibody specific for a protein or a modulator of that protein has no disclosed use in either maintenance of a DNA encoding a protein or the method of making the protein by recombinant means.

Inventions I and V, and I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used to make a protein by recombinant means.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The protein is apparently involved in apoptosis, while the antibody binds to the protein; furthermore, the primary structure of ICE-LAP 3 and 4 reveals nothing about the primary structure of any antibody which binds to them.

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Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The protein is involved in the apoptosis, while the modulator affects ICE-LAP 3 and 4 activities; furthermore, the primary structure of ICE-LAP 3 and 4 reveals nothing about the structure of any modulator.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the purified polypeptide is not disclosed as useful in a gene therapy method.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. No information is presented regarding the use of ICE-LAP 3 and 4 in a hybridization assay for the DNA encoding each protein

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The antibody is used to detect the protein, while the modulators are used to affect the function of the protein.

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Inventions III and V and IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions. No role in a method of gene therapy has been disclosed for an antibody or a modulator of enzymatic activity.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. No information is presented regarding the use of an antibody specific for a protein in a hybridization assay for the DNA encoding that protein.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. No information is presented regarding the use of a modulator of protein activity in a hybridization assay for the DNA encoding that protein.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

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inventions are not disclosed as capable of use together and have different functions. A treatment method involving gene therapy has no role in a method of screening.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification or because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. Furthermore, restriction for examination purposes as indicated is proper because the search required for any one Group is not required for another Group.

Claims 24 and 25 link(s) inventions II and V. If either Group is elected, these claims will only be examined for the elected subject matter.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The inventions are distinct, each from the other because of the following reasons:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703) 308-4201. The examiner can normally be reached on 8:15-12:15 M, 8:15-1:15 Tu-F.

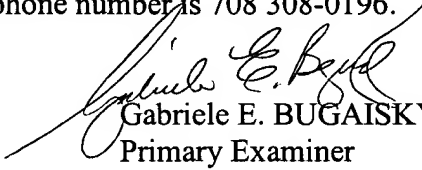
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

**GABRIELLE BUGAISKY
PRIMARY EXAMINER**

**GABRIELLE BUGAISKY
PRIMARY EXAMINER**


Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

September 26, 2002